Technical Service Manual

STIMPOD™

NMS410/450 CE 0120

XAVANT TECHNOLOGY

XM400-30A04 v2.0

STIMPOD™

NMS410/450 CE 0120

Contents

		Page
1.	**Performance test for the StimPod NMS410/450**	**2**
1.1)	Performance tests at the site of use	2
1.1.1)	Nerve Locating Mode	2
1.1.2)	Combined Nerve Mapping/Nerve Locating Mode	2
1.1.3)	Neuromuscular Blocking Agent Mode (NMBA Mode)(NMS450 only)	2
2.	**Test instructions for the safety checks (STK)**	**3**
2.1)	Measuring Equipment	3
2.2)	Checking the external condition of the device	3
2.3)	Performance Testing	3
2.4)	Checking and measuring the Stimpod Output;	3
2.4.1)	Pulse Width test (Locate mode, Locating cable)	3
2.4.2)	Frequency test (Locate mode, insert Locating cable)	3
2.4.3)	Stimulus current test (Locate Mode, Insert Locating cable)	4
2.4.4)	Stimulus current test (Locate Mode, Insert Map/Locating cable)	4
2.4.5)	Stimulus current test (Mapping Mode, Insert Map/Locating cable)	5
2.4.6)	Stimulus current test (NMBA Mode, Insert NMBA cable)	5
2.4.7)	Default Settings	6
3.	**Replacing the electrode cable**	**6**
4.	**Repair address**	**6**
	Appendix: Report Template	

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XAVANT TECHNOLOGY

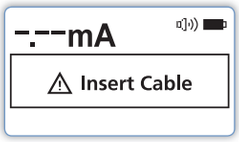
1. Performance test for the StimPod NMS410/450

Before operating and using the device a performance test must be carried out at the site of use in compliance with § 5 MPBetreibV.

1.1 Performance tests at the site of use

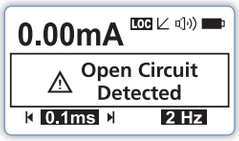
- Insert the batteries and switch on the device.
  The following screen should appear on the display.

followed by

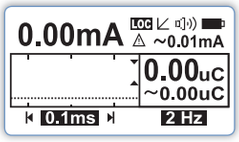


1.1.1. Nerve Locating Mode

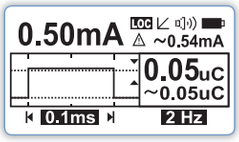
- **Insert the Nerve Locating Cable.**
  The following screen should appear on the display.



- The LED should flash RED and no audible feedback should be heard.
- Short-circiut the needle connector and the ECG connector.
  The following screen should appear on the display.

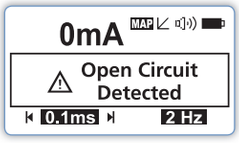


- The LED should flash GREEN and if sound is enabled in the menu a beep should be heard each time a stimulus is delivered.
- Stimulus should occur at the set frequency. (1,2 or 5Hz).
- Use the adjusting wheel and slowly increase the current to 5.00mA.
- Monitor that the stimulating waveform, measured and displayed in the diagnostic window is square and the top part of the wave touches the dotted line, which represents the current setting as shown below.

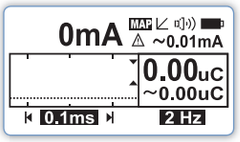


1.1.2. Combined Nerve Mapping/Nerve Locating Mode

- **Insert the Combined Nerve Mapping/ Nerve Locating Cable.**
  The following screen should appear on the display.



- The LED should flash RED and no audible feedback should be heard.
- Short-circuit the Nerve Mapping probe and the ECG connector.
  The following screen should appear on the display.

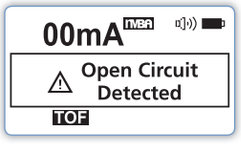


- The LED should flash GREEN and if sound is enabled in the menu a beep should be heard each time a stimulus is delivered.
- Stimulus should occur at the set frequency, (1,2 or 5 Hz).
- Use the adjusting wheel and slowly increase the current to 20mA.
- Monitor that the stimulating waveform, measured and displayed in the diagnostic window is square and that the top part of the square wave touches the dotted line, which represents the current setting.

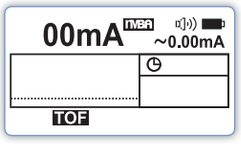
In order to test the Nerve Locating connection and device functionality follow the instructions in 1.1.1.

1.1.3. Neuromuscular Blocking Agent Mode (NMBA Mode) (NMS450 only)

- **Insert the NMBA Cable.**
  The following screen should appear on the display.



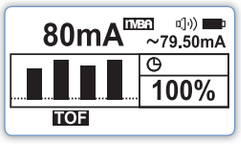
- Ensure that the device is in 'TOF' mode.
- Short-circuit the red and black electrode connectors.



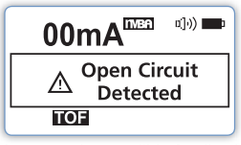
- Use the adjusting wheel and increase the current to 80mA.
- Press the 'play/pause' button while shaking the accelerometer.

The NMS450 should respond as follows:

- The LED should flash GREEN in accordance with the four stimulations.
- Each stimulation should be accompanied by an audible 'beep'.
- In 'Diagnostic window' four bars of different heights should indicate that the accelerometer detected movement.
- Monitor the actual current delivered to ensure that the warning sign does not appear.



- Seperate the red and black electrode connectors to cause an open circuit between them.
- Press the 'play/pause' button.
  The following screen should appear on the display.



- The LED should flash RED and no audible feedback should be heard.

If the STIMPOD malfunctions in any of these performance tests, it should be checked by the relevant technical department in accordance with the following test instructions.

2. Test instructions for the safety checks (STK)

Section 6 of the MPBetreibV specifies that safety checks should be performed by the user.
The safety check should be performed by qualified staff (§ 6, para 4 MPBetreibV) in accordance with the following test instructions.

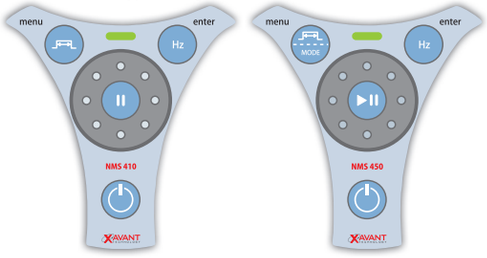
- Print the Report Template.

2.1 Measuring Equipment

The following measuring and testing equipment is required:
- Storage Osciloscope
- 20 kOhm measuring resistor
- 4,5kOhm measuring resistor
- 4 x AAA batteries

2.2 Checking the external condition of the device

(Check the following and tick the corresponding check box in the Report Template.)
- Check that the housing/ connectors and cables are intact and clean (Disinfect the housing/ connectors and cables if they are contaminated with blood or medication.)
- Check that the keypad is legible.



- Check that the battery cover is legible.
- Switch unit on and verify that the display is working.
- Connect a locate cable and verify that the current can be increased using the keypad dial.
- Verify that the pulse width can be changed using 'pulse width' button on the keypad.
- Verify that the frequency can be changed using the 'frequency' button on the keypad.
- Verify that the menu can be accessed using the 'menu' button.
- Connect a locate cable. Verify that the pause button operated when pressed.
- Check that the enclosure, screen, keypad is clean.
- Check that the Claw operates correctly.
- Inspect the keypad to ensure that it is even and flat on the front cover.

Old Version

New Version

2.3 Performance Testing

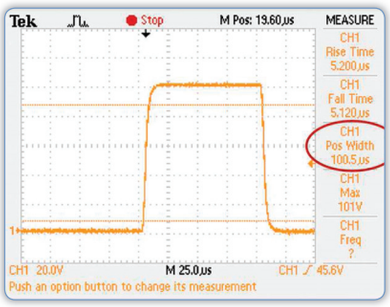
- Carry out performance test according to 1.1 and 1.2.

2.4 Checking and measuring the Stimpod Output

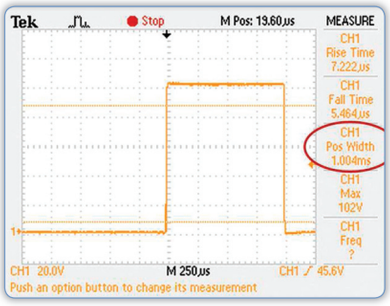
2.4.1. Pulse Width test (Locate mode, Locating cable)

Scope settings are as follow:

- **Channel 1 settings**
  - Coupling DC
  - Probe 10X voltage
  - Invert off
- **Probe**
  - 10X
- **Horizontal Setting**
  - 25µs/Div
- **Vertical Setting**
  - 20V/Div
- *Insert the Locate Cable.*
- *Connect a 20KΩ load.*
- *Adjust the Current to 5mA.*
- *Adjust the frequency to 5Hz.*
- *Adjust the **Pulse Width** to 0.1ms.* [1]



- *Record the Pulse Width on the Report Template.*
- *Adjust the **Pulse Width** to 1ms.*[1]



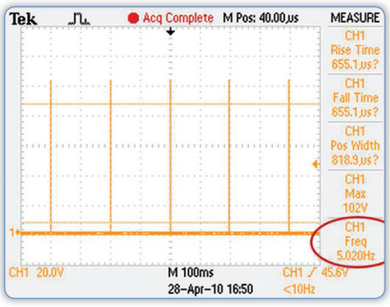
- *Record the **Pulse Width** on the Report Template.*

2.4.2 Frequency test (Locate mode. Insert Locating cable)

Scope settings are as follow:

- **Channel 1 settings**
  - Coupling DC
  - Probe 10X voltage
  - Invert off
- **Probe**
  - 10X
- **Horizontal Setting**
  - 100ms/Div
- **Vertical Setting**
  - 20V/Div

- *Connect a 20KΩ load.*
- *Adjust the Current to 5mA.*
- *Adjust **Frequency** to 5Hz.*
- *Adjust the Pulse Width to 0.1ms.*



*Record the **Frequency** on the Report Template.*

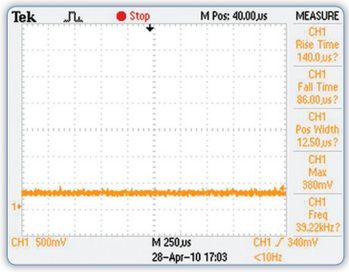
[1] 0.1ms option and 1.0ms option must be selected in the SETUP MENU PULSE WIDTH.

2.4.3 Stimulus current test (**Locate Mode,** Insert Locating cable)

Scope settings are as follow:

- **Channel 1 settings**
  - Coupling DC
  - Probe 10X voltage
  - Invert off
- **Probe**
  - 10X
- **Horizontal Setting**
  - 250µs/Div
- **Vertical Setting**
  - 500mV/Div

- *Connect a 20KΩ load accross the needle and the ECG clip connector.*
- *Adjust the Frequency to 5Hz.*
- *Adjust the Pulse Width at 1ms.*
- *Adjust the **Current** to 0mA.*

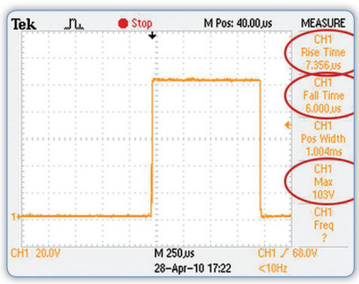


- *Check that there is no stimulating pulse.*
  If a pulse is present:
- *Record the **Voltage** on the Report Template.*
- *Calculate the current: Current = $\frac{Voltage}{20\,000\Omega}$*
- *Record the **Current** on the Report Template.*

Scope settings are as follow:

- **Channel 1 settings**
  - Coupling DC
  - Probe 10X voltage
  - Invert off
- **Probe**
  - 10X
- **Horizontal Setting**
  - 250µs/Div
- **Vertical Setting**
  - 20V/Div

- *Connect a 20KΩ load.*
- *Adjust the Frequency to 5Hz.*
- *Adjust the Pulse Width at 1ms.*
- *Adjust the **Current** to 5mA.*



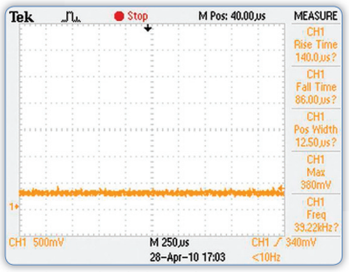
- *Record the **Voltage** on the Report Template.*
- *Calculate the current: Current = $\frac{Voltage}{20\,000\Omega}$*
- *Record the **Current** on the Report Template.*
- *Record the **Rise Time** on the Report Template.*
- *Record the **Fall Time** on the Report Template.*

2.4.4 Stimulus current test (**Locate Mode,** Insert Map/Locating cable)

Scope settings are as follow:

- **Channel 1 settings**
  - Coupling DC
  - Probe 10X voltage
  - Invert off
- **Probe**
  - 10X
- **Horizontal Setting**
  - 250µs/Div
- **Vertical Setting**
  - 500mV/Div

- *Connect a 20KΩ load across the needle and the ECG clip connector.*
- *Adjust the Frequency to 5Hz.*
- *Adjust the Pulse Width at 1ms.*
- *Adjust the **Current** to 0mA.*

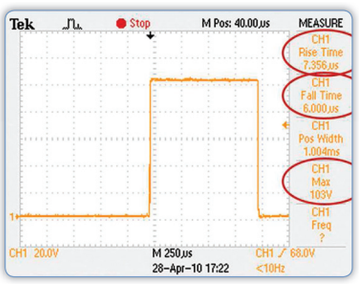


- *Check that there is no stimulating pulse.*
  If a pulse is present:
- *Record the **Voltage** on the Report Template.*
- *Calculate the current: Current = $\frac{Voltage}{20\,000\Omega}$*
- *Record the **Current** on the Report Template.*

Scope settings are as follow:

- **Channel 1 settings**
  - Coupling DC
  - Probe 10X voltage
  - Invert off
- **Probe**
  - 10X
- **Horizontal Setting**
  - 250µs/Div
- **Vertical Setting**
  - 20V/Div

- *Connect a 20KΩ load.*
- *Adjust the Frequency to 5Hz.*
- *Adjust the Pulse Width at 1ms.*
- *Adjust the **Current** to 5mA.*



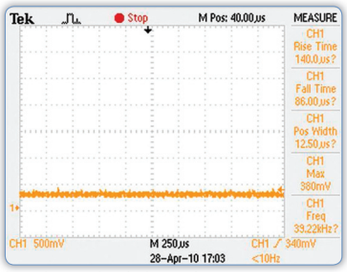
- *Record the **Voltage** on the Report Template.*
- *Calculate the current: Current = $\frac{Voltage}{20\,000\Omega}$*
- *Record the **Current** on the Report Template.*
- *Record the **Rise Time** on the Report Template.*
- *Record the **Fall Time** on the Report Template.*

2.4.5 Stimulus current test (**Mapping Mode,** Insert Map/Locating cable)

Scope settings are as follow:

- **Channel 1 settings**
  - Coupling DC
  - Probe 10X voltage
  - Invert off
- **Probe**
  - 10X
- **Horizontal Setting**
  - 250µs/Div
- **Vertical Setting**
  - 500mV/Div

- *Connect a 20KΩ load accross the Mapping Probe and ECG connector.*
- *Adjust the Frequency to 5Hz.*
- *Adjust the Pulse Width at 1ms.*
- *Adjust the **Current** to 0mA.*



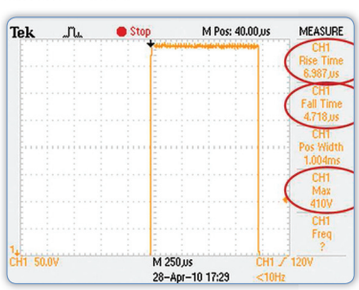
- *Check that there is no stimulating pulse.*

  If a pulse is present:
- *Record the **Voltage** on the Report Template.*
- *Calculate the current: Current = $\frac{Voltage}{20\,000\Omega}$*
- *Record the **Current** on the Report Template.*

Scope settings are as follow:

- **Channel 1 settings**
  - Coupling DC
  - Probe 10X voltage
  - Invert off
- **Probe**
  - 10X
- **Horizontal Setting**
  - 250µs/Div
- **Vertical Setting**
  - 50V/Div

- *Connect a 20KΩ load.*
- *Adjust the Frequency to 5Hz.*
- *Adjust the Pulse Width at 1ms.*
- *Adjust the **Current** to 5mA.*



- *Record the **Voltage** on the Report Template.*
- *Calculate the current: Current = $\frac{Voltage}{20\,000\Omega}$*
- *Record the **Current** on the Report Template.*
- *Record the **Rise Time** on the Report Template.*
- *Record the **Fall Time** on the Report Template.*

2.4.6 Stimulus current test (**NMBA Mode,** Insert NMBA cable)

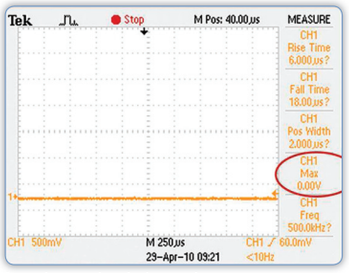
Stimpod settings are as follow:

- Make sure the mode of operation is TWI.
- Frequency set at 5Hz.

Scope settings are as follow:

- **Channel 1 settings**
  - Coupling DC
  - Probe 10X voltage
  - Invert off
- **Probe**
  - 10X
- **Horizontal Setting**
  - 250µs/Div
- **Vertical Setting**
  - 500mV/Div

- *Connect a 4.5KΩ load accross the two ECG connectors.*
- *Adjust the Frequency to 5Hz.*
- *Adjust the **Current** to 0mA.*



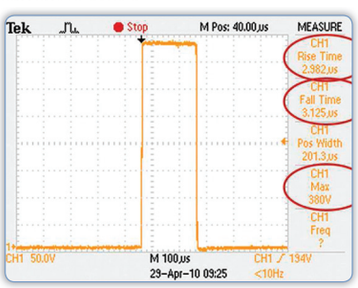
- *Check that there is no stimulating pulse.*

  If a pulse is present:
- *Record the **Voltage** on the Report Template.*
- *Calculate the current: Current = $\frac{Voltage}{4\,500\Omega}$*
- *Record the **Current** on the Report Template.*

Scope settings are as follow:

- **Channel 1 settings**
  - Coupling DC
  - Probe 10X voltage
  - Invert off
- **Probe**
  - 10X
- **Horizontal Setting**
  - 100µs/Div
- **Vertical Setting**
  - 50V/Div

- *Connect a 4.5KΩ load.*
- *Adjust the **Current** to 80mA.*



- *Record the **Voltage** on the Report Template.*
- *Calculate the current: Current = $\frac{Voltage}{4\,500\Omega}$*
- *Record the **Current** on the Report Template.*
- *Record the **Rise Time** on the Report Template.*
- *Record the **Fall Time** on the Report Template.*

2.4.7 Default Settings

Ensure that the device is reset to the following default settings after testing:

- Reset **Pulse Width** options to 0.1ms and 0.3ms.

3. Replacing the electrode cable.

A faulty electrode cable can be easily replaced on site with a new one.
The polarized connector prevents the wrong connection of the electrode cable.

4. Repair address

Manufacturer

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Pretoria, South Africa

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Fax: +27 (0) 12 346 7271

E-Mail: support@xavant.com
Web: www.xavant.com

Checking external condition of the device *(Refer to paragraph 2.2)*	Pass	Fail
Check that the housing/ connectors and cables are intact and clean.	☐	☐
Check that the keypad is legible.	☐	☐
Check that the battery cover is legible.	☐	☐
Switch unit on and verify that the display is working.	☐	☐
Connect a locate cable and verify that the current can be increased using the keypad dial.	☐	☐
Verify that the pulse width can be changed using the 'pulse width' button on the keypad.	☐	☐
Verify that the frequency can be changed using the 'frequency' button on the keypad.	☐	☐
Verify that the menu can be accessed using the 'menu' button.	☐	☐
Connect a locate cable. Verify that the pause button operated when pressed.	☐	☐
Check that the enclosure, screen and keypad is clean.	☐	☐
Check that the Claw operates correctly.	☐	☐
Inspect the keypad to ensure that it is even and flat on the front cover.	☐	☐

Performance Testing *(Refer to paragraph 2.3)*	Pass	Fail
Carry out performance test according to 1.1 and 1.2	☐	☐

Connect a 20kΩ load and set the current to 5mA and frequency to 5Hz

(Refer to paragraph 2.4.1) **Pulse width test (Locate mode, Locate cable)**

Expected values		Variance		5%	
Setting (ms)	Measured (ms)	Min (ms)	Max (ms)	Pass	Fail
0.1		0.095	0.105	☐	☐
1.0		0.950	1.050	☐	☐

Connect a 20kΩ load and set the current to 5mA and frequency to 5Hz

(Refer to paragraph 2.4.2) **Frequency test (Locate mode, Locate cable)**

Expected values		Variance		5%	
Setting (Hz)	Measured (Hz)	Min (Hz)	Max (Hz)	Pass	Fail
5		4.750	5.250	☐	☐

Connect a 20kΩ load and set the pulse width of 1.0ms *(Refer to paragraph 2.4.3)*

Locate Cable (Locate Mode)

Stimulus Current/Rising/Falling Edges

Expected values			Variance		5%		Expected values					
Setting (mA)	Measured (V)	Calculated (mA)	Min (mA)	Max (mA)	Pass	Fail	Setting (mA)	Measured (µs)	Min (µs)	Max (µs)	Pass	Fail
0.00			0.000	0.000	☐	☐			⌜ *Rising Edge (µs)*			
5.00			4.750	5.250	☐	☐	5mA		0.01	10	☐	☐
									⌞ *Falling Edge (µs)*			
							5mA		0.01	10	☐	☐

Connect a 20kΩ load and set the pulse width of 1.0ms *(Refer to paragraph 2.4.4)*

Map/Locate Cable (Locate Mode)

Stimulus Current/Rising/Falling Edges

Expected values			Variance		5%		Expected values					
Setting (mA)	Measured (V)	Calculated (mA)	Min (mA)	Max (mA)	Pass	Fail	Setting (mA)	Measured (µs)	Min (µs)	Max (µs)	Pass	Fail
0.00			0.000	0.000	☐	☐			⌜ *Rising Edge (µs)*			
5.00			4.750	5.250	☐	☐	5mA		0.01	10	☐	☐
									⌞ *Falling Edge (µs)*			
							5mA		0.01	10	☐	☐

Connect a 20kΩ load and set the pulse width of 1.0ms *(Refer to paragraph 2.4.5)*

Map/Locate Cable (Mapping Mode)

Stimulus Current/Rising/Falling Edges

Expected values			Variance		5%		Expected values					
Setting (mA)	Measured (V)	Calculated (mA)	Min (mA)	Max (mA)	Pass	Fail	Setting (mA)	Measured (µs)	Min (µs)	Max (µs)	Pass	Fail
0.00			0.000	0.000	☐	☐			⌜ *Rising Edge (µs)*			
20.00			19.000	21.000	☐	☐	20mA		0.01	10	☐	☐
									⌞ *Falling Edge (µs)*			
							20mA		0.01	10	☐	☐

Connect a 4.5kΩ load *(Refer to paragraph 2.4.6)*

NMBA Cable (NMBA Mode)

Stimulus Current/Rising/Falling Edges

Expected values			Variance		5%		Expected values					
Setting (mA)	Measured (V)	Calculated (mA)	Min (mA)	Max (mA)	Pass	Fail	Setting (mA)	Measured (µs)	Min (µs)	Max (µs)	Pass	Fail
0.00			0.000	0.000	☐	☐			⌜ *Rising Edge (µs)*			
80.00			76.000	84.000	☐	☐	80mA		0.01	10	☐	☐
									⌞ *Falling Edge (µs)*			
							80mA		0.01	10	☐	☐

Default Settings *(Refer to paragraph 2.4.7)*	Pass	Fail
Reset pulse width options to 0.1ms and 0.3ms.	☐	☐